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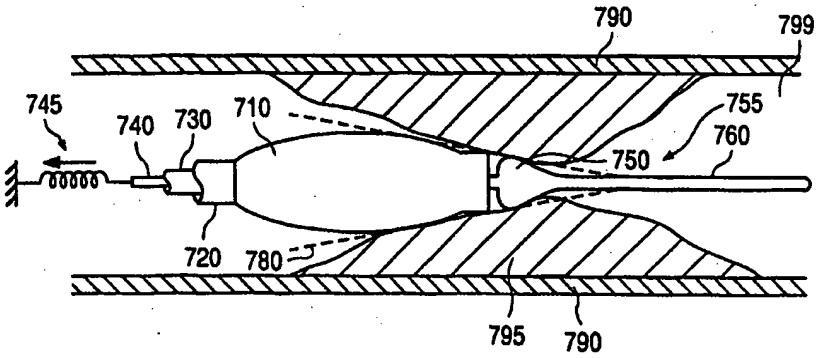

(57) Abstract

A guidewire includes a proximal section; a distal section; and a protruding section, the protruding section being integral with the guidewire and disposed between the proximal and distal sections. The protruding section tapers in the distal direction to smoothly join with the distal section. According to another aspect of the invention, an intravascular catheter includes a catheter shaft having a work element attached to a distal section thereof; a center shaft disposed axially within the catheter shaft, the center shaft having a guidewire lumen therethrough, and a guidewire slidably disposed within the guidewire lumen, the guidewire including an integral and tapered protruding section near the distal tip thereof. When the guidewire is fully proximally retracted, the proximal surface of the protruding section faces and abuts against a corresponding distal-most surface of the catheter shaft to present a gradual transition from the guidewire to the distal section of the catheter shaft. According to another aspect, the present invention provides a percutaneous transluminal coronary angioplasty balloon catheter including a catheter and center shaft, both of which include an axial lumen therethrough. An inflatable balloon is disposed near the distal end of the catheter shaft. The center shaft is disposed within the axial lumen of the catheter shaft. One or both of the catheter and center shafts include either a wire, a coil or a wire braid embedded therein or wound about an outer diameter thereof to enhance torqueability of the balloon catheter.

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IMPROVED GUIDEWIRE, CATHETER AND METHOD OF CROSSING TIGHT INTRAVASCULAR OCCLUSIONS USING SAME

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present inventions pertain to the field of intravascular devices. In particular, the present invention relates to improved catheters and guidewires for use in balloon angioplasty and other types of procedures.

2. Description of the Related Art

Fig. 1 shows the root of the aorta 200 and a right coronary artery, exhibiting both a near total occlusion 110 and total occlusion 120 in a highly tortuous artery 102. The near total and total occlusions 110, 120 are shown in the same artery 102 for illustrative purposes only, as they are unlikely to both be present in the same artery. Such occlusions are often found in patients suffering from atherosclerosis, a condition characterized by an accumulation of fibrous, fatty or calcified tissue in the arteries. As these occlusions partially or totally block the arterial flow, they may be or may have the potential to become life threatening.

Although the majority of interventional procedures such as balloon angioplasty, atherectomy, stenting and the like bring some degree of relief to the patient and improvement in the blood flow, total or near total occlusions are difficult to treat, as the interventional tool, such as the angioplasty balloon, often cannot reach and cross the occlusion site to carry out its intended functions. This is generally referred to as an inability to cross, and is one of the major causes of failures of such procedures.

There has been a long felt need in the cardiovascular medicine and coronary intervention community for effective-tools for crossing and treating

totally and near totally occluded arteries. There are instances, however, where conventional guidewires successfully cross even total occlusions, only to have the interventional procedure itself fail. Indeed, while a small diameter guidewire (typically on the order of 0.014 inches) may cross a given occlusion, the blunt distal end of the catheter may be unable to follow, being necessarily of a substantially greater diameter, This is the situation depicted in Fig. 2. Fig. 2 shows a cross section of a vessel 210, such as an artery, in which an occlusion 220 (also shown in crosssection) almost totally blocks the flow of blood downstream from the occlusion. The occlusion 220 may be may be soft and fatty or hard and calcified, and may be found at a great variety of sites in the arterial system, including the aorta, the coronary and carotid arteries, and peripheral arteries. As shown in Fig. 2, a balloon catheter 270 includes a catheter shaft 250 and an inflatable balloon 260. A center shaft 240, shown in dashed lines, is disposed within the catheter shaft 250, in an interior axial lumen thereof A guidewire 230 is slidably disposed within the center shaft 240. Even when the occlusion 220 is particularly hard and calcified or fibrous in nature, the guidewire 230 may succeed in crossing the occlusion 220. However, the work element of the catheter, such as the inflatable balloon 260, may be unsuccessful in following in the path of the small diameter guidewire 230. The entire assembly must then be retracted in the proximal direction and the catheter removed from the patient's body. Thereafter, other more invasive and traumatic surgical treatment procedures may prove to be necessary to restore a healthy blood flow. Improved catheters and guidewires having enhanced occlusion-crossing characteristics would, therefore, decrease the need for such surgical procedures, decrease the costs of such procedures and speed up the patient's eventual return to regular physical activity.

What are needed, therefore, are improved guidewires and intravascular catheters using such improved guidewires that exhibit improved occlusion-crossing characteristics.

Another common cause of interventional failures, particularly in the case of Percutaneous Translurninal Coronary Angioplasty (PTCA) balloon catheters,

is the inability to push and navigate the balloon catheter to the target lesion site, which may be located distally in a tortuous artery of small diameter. Indeed, balloon catheters, although of potentially great therapeutic value if correctly placed, often cannot navigate the small and tortuous vessels leading to the occlusion to be treated.

What is also needed, therefore, is a balloon angioplasty catheter that is more successful than conventional catheters in navigating through tight and tortuous passageways.

SUMMARY OF THE INVENTION

It is, therefore, an object of the present invention to provide improved guidewires and intravascular catheters using such improved guidewires having improved occlusion-crossing characteristics. It is also an object of the present invention to provide a balloon angioplasty catheter that is more successful than conventional catheters in navigating through tight and tortuous anatomy. It is a further object of the present invention to provide an improved method for crossing an intravascular occlusion, particularly within the context of intravascular balloon angioplasty catheters.

In accordance with the above objects and those that will be mentioned and will become apparent below, an embodiment of a guidewire for an intravascular device according to the present invention includes:

a proximal section having a first outer diameter;

a distal section having a second outer diameter; and

a protruding section, the protruding section being integral with the guidewire and disposed between the proximal and distal sections, the protruding section having a third outer diameter that is greater than the first outer diameter, the protruding section tapering in a distal direction to the second outer diameter to smoothly join with the distal section.

According to other embodiments, the protruding section may have either a generally teardrop shape, a tapered end thereof pointing in the distal direction, a generally acorn-like shape, or a right circular conical shape, with a traumatic

edges. The first and second outer diameters of the guidewire may be substantially equal. The distal section may include one or more tapers. The distal section may include a shapeable portion at a distal tip thereof, the shapeable portion facilitating navigation through tight and tortuous lumens. At least a portion of the distal section may include a spirally wound coil. The guidewire including the protruding section may be formed of a single continuous and substantially homogeneous wire material by selectively removing material from the proximal and distal sections. The selective removal of material from the proximal and distal sections of the guidewire may be carried out by centerless grinding of guidewire stock material. The guidewire may comprise, for example, stainless steel or a nickel titanium alloy.

An intravascular catheter, according to another embodiment of the present invention, comprises:

a catheter shaft, the catheter shaft having a work element attached to a distal section thereof,

a center shaft disposed axially within the catheter shaft, the center shaft having a guidewire lumen therethrough; and

a guidewire slidably disposed within the guidewire lumen, the guidewire including an integral and tapered protruding section near a distal tip thereof, wherein, when the guidewire is fully retracted in a proximal direction, a proximal surface of the protruding section parallel to a longitudinal axis of the catheter faces and abuts against a corresponding distal-most surface of the catheter shaft to present a gradual transition from the guidewire to the distal section of the catheter shaft.

According to further embodiments, the work element may be an inflatable balloon. The guidewire may include a flexible terminal section distal to the protruding section, the terminal section having an outer diameter substantially equal to the outer diameter of the section of the guidewire proximal to the protruding section. The terminal section may have a length that is sufficient to cross common intravascular occlusions. The protruding section may have a generally teardrop shape, a tapered portion thereof pointing in the

distal direction, a generally fight circular conical shape, with atraumatic rounded edges or other suitable shapes, such as an acorn-like shape. Either or both of the catheter and center shafts may include a spirally wound wire or coil, or a wire braid embedded therein or wound thereabout, to enhance the torqueability of the catheter in tortuous and tight vessels. The terminal section of the guidewire may include a coil wound about an outer diameter thereof The distal most portion of the terminal section may be shaped to facilitate navigation through tortuous vessels.

According to another embodiment, the method for crossing an intravascular occlusion using a catheter and a guidewire including a distal tapered protruding section and a flexible terminal section distal to the protruding section, according to the present invention, comprises the steps of:

advancing the guidewire through a patient's vasculature until the occlusion is reached;

further advancing the guidewire until the terminal section crosses the occlusion and the tapered protruding section reaches the occlusion;

sliding the catheter over the guidewire by pushing a proximal end thereof until a distal end of the catheter abuts a proximal surface of the tapered protruding section; and

while applying a biasing force to the guidewire in a proximal direction, pushing the proximal end of the catheter to advance both the tapered protruding section of the guidewire and the catheter distal end until the occlusion is crossed. In this manner, the tapered protruding section and the distal end of the catheter together present a substantially smoothly tapered profile to the occlusion.

According to a still further embodiment, the catheter may have a torqueable shaft, and the sliding and pushing steps may also include applying torque to the proximal end of the catheter, the torque being transmitted via the torqueable shaft to the distal end thereof.

A percutaneous transluminal coronary angioplasty (PTCA) balloon catheter, according

to another embodiment of the present invention, comprises:

a center shaft, the center shaft including an axial guidewire lumen;

a catheter shaft, the catheter shaft including an axial lumen therethrough in which the center shaft is disposed, at least one of the catheter shaft and the center shaft including one of a wire, a coil and a wire braid embedded therein or wound about an outer diameter thereof, the wire, coil or wire braid enhancing a torque transmission ability of the PTCA catheter; and

an inflatable balloon disposed near a distal end of the catheter shaft.

According to other embodiments, the coil may be either single or multifilar. Either or both of the catheter and center shafts may comprise one or more materials selected from the group consisting of PEBAX, polyurethane, nylon and polyimide. A guidewire may be slidably disposed within the guidewire lumen, the guidewire including an integral and tapered protruding section near a distal tip thereof.

BRIEF DESCRIPTION OF THE DRAWINGS

For a further understanding of the objects and advantages of the present invention reference should be made to the following detailed description, taken in conjunction with the accompanying figures, in which:

Fig. 1 is a simplified diagram of a right coronary artery, showing both near total and total chronic occlusions in a highly tortuous artery.

Fig. 2 is a cross section of an occluded artery, illustrating the difficulty of crossing tight stenoses with conventional catheters, such as balloon angioplasty catheters.

Fig. 3 shows one embodiment of an improved guidewire according to the present invention.

Fig. 4 illustrates another embodiment of the improved guidewire according to the present invention.

Fig. 5 shows yet another embodiment of the improved guidewire according to the present invention.

Fig. 6A shows an embodiment of a balloon catheter according to the present invention, with the guidewire extended in the distal direction.

Fig. 6B shows the balloon catheter of Fig. 6A, with the guidewire retracted in the proximal direction.

Fig. 7A shows a cross-section of an occluded artery, illustrating aspects of the method according to the present invention.

Fig. 7B shows the cross-section of Fig. 7A, illustrating further aspects of the method according to the present invention.

Fig. 8 shows an example of an arterial stent, to illustrate the tendency of conventional balloon angioplasty catheter devices to become caught in the stent wire meshwork.

Fig. 9 shows a balloon angioplasty catheter according to another embodiment of the present invention, whose catheter shaft and/or center shaft has enhanced torqueability characteristics.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention is partly predicated upon the identification of two major problems inherent in conventional intravascular catheters in general, and balloon angioplasty catheters in particular. The first of these problems is explained below with reference to Fig. 2. As shown in Fig. 2, while the guidewire 230 often succeeds in crossing a tight or even a total occlusion, the distal portion of the catheter, including the inflatable balloon often cannot follow. This failure to cross is at least partly attributable to the blunt profile of the distal tip of the catheter. Indeed, even when the leading distal surface 280 of the catheter 270 is tapered as shown in Fig. 2, it nevertheless presents a large profile to the occlusion 220. Moreover, the occlusion 220 may be substantially unyielding to such a blunt surface, especially when the occlusion 220 is highly calcified and/or fibrous. Efforts to reduce the profile of the leading distal surface 270 are inherently limited to a dimension that is slightly larger than the inner diameter of the center lumen 240 shown in dashed lines in Fig. 2. This inner diameter of the center shaft 240 is typically on the order of 0.017 inches

for a guidewire having an outer diameter of about 0.014 inches. As the catheter shaft 240 surrounding the axial lumen of the center shaft 240 cannot have zero thickness, a typical outer diameter for the distal leading surface 280 of the catheter 250 is typically about 0.021 to about 0.035 inches. Because of this large leading surface, conventional catheters often fail-to cross very tight occlusions, as their blunt distal leading surfaces exert most of the applied force in a direction parallel to the longitudinal axis of the catheter, and very little in a radial direction relative thereto. However, it is in the radial direction (toward the vessel walls) that the forces are most effective in pushing and compressing occlusive tissue to allow the catheter to follow the path of the guidewire.

The present invention addresses this first problem by providing a guidewire having a number of characteristics that enhance a catheter's ability to cross near total and total occlusions. One of these is believed to be the ability of the guidewires according to the present invention to exert a greater portion of the applied force in the radial direction, to thereby separate and compress the occlusive tissue.

An embodiment of a guidewire having such characteristics is shown in Fig. 3. Fig. 3 shows the distal portion of the guidewire according to the present invention, the remaining portion thereof being symbolized by dashed lines. The guidewire 300 according to the present invention includes a proximal portion 310 and a flexible terminal section 330 at the end of which is a distal tip 340. Between the proximal portion 310 and the terminal section 330 is a tapered protruding section 320. The tapered protruding section 320 is integral to the guidewire 300, meaning that the proximal section 310, the tapered protruding section 320 and the terminal section 320 are formed from a single and continuous and substantially homogeneous piece of guidewire stock material, such as stainless steel wire or a Nickel-Titanium alloy wire, for example. Indeed, the guidewire stock material may be a stainless steel wire with an outer diameter ranging from about 0.021 to about 0.035 inches. For example, the guidewire stock material may have an outer diameter of about 0.022 inches. In one illustrative embodiment of the present invention, using centerless grinding

techniques known to those of skill, the proximal section 310 and the flexible terminal section 330 may be ground to an outer diameter AA and CC of about 0.014 inches. The length E of the terminal section 330 should be chosen according to length of the occlusion the guidewire must cross. Typically, however, the length E of the terminal section 330 should be selected within the range of about 5 to about 30 cm.

The protruding section 320 is carefully ground to a generally teardrop shape, a generally right circular cone shape with atraumatic rounded edges or some other similar shape. The greatest outer diameter BB, at or near the proximal portion of the tapered protruding section 320, is about 0.016 to about 0.022 inches in diameter, when starting from 0.022 inches outer diameter guidewire stock. The longitudinal dimension D of the tapered protuberancc 320 may range from about 0.05 to about 0.5 inches in length. Longer longitudinal lengths D may lead to a greater stiffness of that section of the guidewire 300. Preferably, the dimension D should be selected within the range of about 0.01 to about 0.025 inches. The exterior surface 350 of the protruding section 320 may be ground to smoothly curve from the proximal end of the terminal section 330 to the proximal-most portion of the protruding section 320. Alternatively, the exterior surface 350 of the protruding section 320 may be rectilinear or even piece-wise rectilinear, and the protruding section 320 may resemble more a right circular cone having rounded, atraumatic rounded edges. The base of such a cone shaped protuberance 320 would face the proximal direction (toward the physician) and the tapered section thereof would be directed in the distal direction (away from the physician and toward the distal. tip 340).

As with the design and shape of the tapered protruding section 320, the design and shape of the terminal section 330 may be varied to suit the preferences of the treating physician as well as the location and characteristics of the target occlusion. Indeed, as shown in Fig. 4, the flexible terminal section 430 of the guidewire 400 may include a spirally wound coil 450 (shown in cross-section for clarity) wound about the outer diameter of the terminal section 430. The spirally wound coil 450 may be soldered or welded, for example, at

the proximal and distal ends thereof Moreover, the spirally wound coil 450 may also be soldered welded or otherwise bonded for example, at intermediate points 432 where the guidewire 430 tapers. The terminal section 430 may be ground to substantially the same outer diameter as that of the proximal section 410, or may be ground to a greater diameter or a smaller diameter and reinforced with spirally wound coil or wire 450. As shown in Fig. 4, the terminal section 430 tapers at 432 to a smaller diameter than the proximal section 410. The coil 450 may be single or multifilar. An atraumatic distal cap 460 may cover the distal tip of the terminal section 430. The distal cap 460 may be a solder ball, for example. To aid in navigating tight and tortuous vessels, the terminal section 430 may include a shaped portion 440, which may assist the treating physician in guiding the guidewire to its intended destination. For example, by rotating the guidewire 400, the treating physician may cause the guidewire 400 to follow the arterial branch 130, as opposed to the arterial branch 140, shown in Fig. 1. As shown in Fig. 5, the flexible terminal section 530 of the guidewire 500 may be further include one or more tapers, one of which is shown at reference numeral 5 1 0. Alternatively still, the features described relative to Figs. 3, 4 and 5 may be used in combination. For example, a tapered flexible terminal section 510, as shown in Fig. 5 may be used without or in conjunction with wire or coil windings 450, as shown in Fig. 4, or with or without a shapeable portion 440, as shown in Fig. 4.

Figs. 6A and 6B show an embodiment of a balloon angioplasty catheter 600 according to the present invention using a guidewire 655 according to the present invention. Fig. 6A shows a balloon angioplasty catheter and guidewire assembly, wherein the guidewire 655 is extended in the distal direction, whereas Fig. 6B shows the same assembly wherein the guidewire 655 according to the present invention is retracted in the proximal direction.

Turning first to Fig. 6A, the catheter 600 comprises a catheter shaft 620, a center shaft 630 disposed within an axial lumen of the catheter shaft 620, and an inflatable balloon section 610. The inflatable section 610 is in fluid communication with an inflation fluid reservoir located outside the patient's

body, the inflation fluid (not shown) travelling through an annular space between the center shaft 630 and the catheter shaft 620 to the inflatable section 610, as is known in the art. Alternatively, dedicated fluid inflation and fluid evacuation lumens may be disposed within the catheter shaft, as is also known in the art. The guidewire 655 includes a proximal section 640, which extends from outside the patient's body to the tapered protuberance 650. The proximal section 640 is disposed and slides within the axial lumen of the center shaft 630. The tapered protuberance 650 is distal to the inflatable section 610, as is the terminal section 660. Fig. 6A and 6B are shown with a flexible terminal section 660 having a shaped portion 670. However, the terminal section 660 need not have such a shaped portion 670 and may have a distal tip that is, for example, aligned with the guidewire's longitudinal axis.

As shown in Fig. 6B, the guidewire 655 is fully retracted in the proximal direction. In this configuration, the proximal surface 652 of the protruding section 650 that is perpendicular to the longitudinal axis of the catheter 600 faces and abuts against a corresponding distal-most surface 622 of the catheter shaft 620. In this position, the catheter and guidewire 655 assembly present a gradually tapered and substantially smooth transition from the guidewire 655 to the distal section of the catheter shaft 620. This gradual and tapered transition is shown as envelope 680, shown in dashed lines in Fig. 6B. In this manner, the distal section of the catheter shaft 620 no longer presents a blunt surface to the target occlusion. According to the present invention, the tapered protuberance 650 smoothly varies in its outer diameter from the outer diameter of the terminal section 660 to an outer diameter that is substantially equal (or just smaller) than the outer diameter of the distal most surface 622 of the catheter shaft 620. It is this smoothly tapered profile that is presented to the target occlusion, the protuberance 650 easing the transition between the guidewire 655 and the catheter work element, such as the inflatable balloon 610.

The operation of the catheter-guidewire assembly and aspects of the method for crossing an intravascular occlusion according to the present invention are shown in Figs. 7A and 7B. Figs. 7A and 7B show, in cross-

section, a biological vessel 790 such as an artery. A near total occlusion 795, also shown in cross-section for clarity, blocks a significant amount of blood flow.

According to the present invention, the physician advances the guidewire 755 through the patient's vasculature, by pushing and guiding the guidewire 755 through appropriate pathways until the occlusion 795 is reached. The guidewire 755 is then further advanced, as shown in Fig. 7A, until the flexible terminal section 760 crosses the occlusion 795 and the tapered protruding section 750 itself reaches the occlusion 795. As the terminal section 760 of the guidewire 755 may be, for example, only about 0.014 inches at its outer diameter, the terminal section 760 often succeeds in crossing even total occlusions. It is at this point, however, that conventional catheters often experience failure to cross, as is described in detail relative to Fig. 2. According to the present invention, however, the success rate of crossing tight occlusions may be improved using the guidewire 755 and method according to the present invention. The catheter shaft 720, together with the balloon 71 0, is slid over the proximal section 740 of the guidewire 755 by pushing the proximal end of the catheter shaft 720 until the distal-most surface 722 (shown in Fig. 7A) of the catheter abuts the proximal surface or extremity 752 (also shown in Fig. 7A) of the tapered protruding section 750. This catheter-guidewire assembly thus forms a smoothly tapered envelope, as shown at reference numeral 780 in Fig. 7B. Thereafter, the treating physician applies a biasing force in a proximal direction (symbolized in Fig. 7B by the spring and arrow 745) to the guidewire 755. This maintains the guidewire 755 firmly against the distal-most surface 722 to minimize the movement of the guidewire 755 relative to the catheter shaft 720. The physician then pushes the proximal end of the catheter to advance both the tapered protruding section 750 of the guidewire 75 5 and the catheter work element, such as the inflatable balloon 7 1 0, until the occlusion 795 is crossed. In this manner, the tapered protruding section 750 and the distal surface 722 of the catheter together present a substantially smoothly tapered profile to the occlusion 795. It is believed that by providing a smoothly varying

transition from the guidewire 755 to the distal surface 722 of the catheter, a portion of the forces applied by the physician as he or she pushes the catheter shaft 720 in the distal direction are redistributed in the radial direction and against the occlusion. These radial forces are believed to increase as the catheter and guidewire assembly is advanced across the occlusion 795, as the tapered protuberance 750 wedges into and enlarges the passageway through the occlusion 795 through which the terminal section 760 of the guidewire 755 traveled. As the occlusion 795 is pushed and/or compressed toward the vessel walls 790, the catheter's inflatable balloon 710 may be advanced into position fully across the occlusion 795, whereupon the physician may inflate the balloon 710 and carry out the intended balloon angioplasty procedure.

It should be noted that, although the operation of the guidewire 755 has been described relative to a balloon catheter, the guidewire 755 and the use thereof is not limited thereto. Indeed, the guidewires according to the present invention, as shown in Figs. 3, 4 and 5 may be utilized in. conjunction with most any over-the-wire intravascular device presenting an otherwise blunt leading distal surface that must cross tight, hard, fibrous, fibro-calcific, near total or total occlusions. For example, the guidewires according to the present invention may be utilized with atherectomy catheters, or in combination with most any catheter having a blunt distal leading surface.

As alluded to above, the present invention is partly predicated upon the identification of two major problems inherent in conventional intravascular catheters in general, and balloon angioplasty catheters in particular. The first problem, namely the inability to cross tight occlusions, is addressed above, relative to the improved guidewires shown in Figs. 3, 4 and 5 and to the catheter-guidewire assemblies shown in Figs. 6A, 6B, 7A and 7B.

The second problem identified and addressed by the present invention relates to the inability of conventional balloon angioplasty catheters to transmit torque. Indeed, conventional balloon angioplasty catheters are not torqueable or exhibit poor torque transmission characteristics. This means that conventional balloon catheters do not readily transmit the torque applied by the physician at

the proximal end of the catheter shaft to the distal. end of the catheter. Instead, conventional balloon angioplasty catheters, when torque is applied, tend to "wind-up" and store the torque by elastically twisting rather than transmitting the torque to the distal end of the catheter. The ability to transmit applied torque to the distal end of the device, however, is relevant to the physician's ability to navigate the device through highly tortuous vasculature. Indeed, as the device turns about its longitudinal axis, the fictional forces against the vessel walls are more evenly distributed than if the device did not rotate. Therefore, the lack of torqueability of conventional balloon angioplasty catheters directly affects the physician's ability to place the balloon angioplasty device at the target location.

Advances in the treatment of arterial stenoses have led to the development and widespread use of arterial stents, which are annular or tubular segments of wire mesh or struts that are placed within an artery to keep the vessel open by exerting radially directed forces on the vessel walls. A simplified depiction of an arterial stent 800 is shown in Fig. 8. The modem trend has been the placement of increasingly longer, increasingly flexible and highly angulated stents and the placement of stents in increasingly tortuous locations. However, should balloon angioplasty interventions be required after a stent or stents are placed in an artery, the great length and increasingly sharp curves of such stents have been found to hamper the physician's ability to negotiate conventional balloon catheters past these obstacles. Indeed, the lack of or poor torqueability of conventional balloon angioplasty catheters has resulted in balloon catheters being caught in or catch the wire meshwork or wire struts of such stents, particularly at the locations indicated by the arrows 8 1 0 in Fig. 8. If such balloon angioplasty catheters were torqueable, that is, able to transmit applied torque to the distal end of the catheter, the distal portion thereof could be rotated, thus reducing the probability that such a catheter would become entangled or stuck in the stent.

The present invention also addresses this problem. Reference is now made to Fig. 9. According to the present invention, the balloon angioplasty catheter 900 includes a shaft or shafts having torque-enhancing characteristics.

The 2 to 5 French crossing profile balloon angioplasty catheter of Fig. 9 (only the distal part of which is shown in Fig. 9) includes a catheter shaft 920. An inflatable balloon 910 is attached to the catheter shaft. The catheter shaft 920 includes an axial lumen, through which a center shaft 930 is disposed. The inflatable balloon 910 may be in fluid communication with an inflation fluid reservoir located outside the patient's body, the inflation fluid (not shown) travelling through an annular space between the center shaft 930 and the catheter shaft 920, as is known in the art. Alternatively, dedicated fluid inflation and fluid evacuation lumens may be disposed within the catheter shaft 920, as is also known in the art. A guidewire 940 is disposed and is adapted to slide within the center shaft's axial lumen. According to the present invention, the catheter shaft 920 may include a wire, a coil or a wire mesh wound about the outer diameter of the catheter shaft. Alternatively, the wire, the coil or the mesh may be embedded within and/or bonded to the catheter shaft 920. Also according to the present invention, the center shaft 930 may also include a wire, coil or mesh embedded within, bonded thereto, and/or wound about the outer diameter thereof The thickness of the wire, coil or wire mesh may be selected within a range of about 0.001 to about 0.005 inches. For example, the center shaft may have an axial lumen of 0.017 inches and a spirally woundwire of about 0.002 inches in diameter. Either or both the catheter and center shafts 920, 930 may include an extrudable plastic material, such as, for example, PEBAX, polyurethane, nylon and polyimide or a blend or blends thereof By selecting the material, the wire, coil or braid configuration, the number of such wires and the diameters thereof, excellent pusbability and torqueability characteristics may be achieved for both the catheter shaft and/or the center shaft, thereby increasing those characteristics for the overall catheter device itself.

Various combinations are possible: for example, the catheter shaft may include a spirally wound coil embedded therein and the center shaft may include a wire mesh bonded thereto, or may not include any wire, coil or mesh. The wire, coil or mesh on or in the catheter shaft 920 and/or the center shaft 930 are

believed to increase the torque transmission characteristics of the catheter while maintaining its flexibility, and to allow the physician to cause the distal end of the device to smoothly rotate under the influence of a torque applied to the proximal end thereof. By virtue of such torque enhancing features, the balloon angioplasty catheters according to the present invention are believed able to navigate highly tortuous vessels and negotiate even long and highly curved or angulated. stents with greater success than is possible using conventional balloon angioplasty catheters.

The catheter shown in Fig. 9 may be advantageously utilized in combination with the improved guidewires according to the present invention, as shown in Figs. 3, 4 and 5. For example, the catheters shown in Figs. 6A, 6B, 7A and 7B may be provided with catheter shafts 620, 720 and/or center shafts 630, 730 having torque transmission enhancing features, as shown in Fig. 9. Such a balloon angioplasty catheter-guidewire assembly is believed to exhibit superior occlusion crossing and torque transmission characteristics, thus increasing the physician's ability to negotiate stents and even highly tortuous vessels to deliver the device to the target occlusion. Once delivered to the appropriate location within the patient's vasculature, the improved occlusion crossing characteristics of the balloon angioplasty catheter according to the present invention are believed to increase the odds of a successful treatment.

While the foregoing detailed description has described preferred embodiments of the present invention, it is to be understood that the above description is illustrative only and not limiting of the disclosed invention. For example, other shapes for the tapered protuberance will undoubtedly occur to those of skill in the art, such as a generally acorn-shaped protuberance. Moreover, other means for enhancing the torque transmission characteristics of catheter and center shafts of balloon angioplasty catheters will no doubt occur to the skilled artisan. Further modifications will occur to those of skill in this art, and all such modifications are deemed to fall within the scope of the present invention. Thus, the present invention is to be limited only by the claims as set forth below.

What is claimed is:

1. A guidewire for an intravascular device, comprising:

a proximal section having a first outer diameter;

a distal section having a second outer diameter; and

a protruding section, the protruding section being integral with the guidewire and disposed between the proximal and distal sections, the protruding section having a third outer diameter that is greater than the first outer diameter, the protruding section tapering in a distal direction to the second outer diameter to smoothly join with the distal section.

2. The guidewire according to claim 1, wherein the protruding section has one of a generally teardrop shape, a tapered end thereof pointing in the distal direction, and a right circular conical shape, with atraumatic edges.

3. The guidewire according to claim 1, wherein the first and second outer diameters are substantially equal.

4. The guidewire according to claim 1, wherein the distal section includes at least one taper.

5. The guidewire according to claim 1, wherein the distal section includes a shapeable portion at a distal tip of the distal section, the shapeable portion facilitating navigation through tight and tortuous lumens.

6. The guidewire according to claim 1, wherein at least a portion of the distal section includes a spirally wound coil.

7. The guidewire according to claim 1, wherein the guidewire including the protruding section is formed of a single continuous and substantially homogeneous wire material by selectively removing material from the proximal and distal sections.

8. The guidewire according to claim 7, wherein the selective removal of material from the proximal and distal sections of the guidewire is carried out by centerless grinding of guidewire stock material.

9. The guidewire according to claim 1, wherein the guidewire comprises one of stainless steel and nickel titanium alloy.

10. An intravascular catheter, comprising:

a catheter shaft, the catheter shaft having a work element attached to a distal section thereof,

a center shaft disposed axially within the catheter shaft, the center shaft having a guidewire lumen therethrough; and

a guidewire slidably disposed within the guidewire lumen, the guidewire including an integral and tapered protruding section near a distal tip thereof, wherein, when the guidewire is fully retracted in a proximal direction, a proximal surface of the protruding section parallel to a longitudinal axis of the catheter faces and abuts against a corresponding distal-most surface of the catheter shaft to present a gradual transition from the guidewire to the distal section of the catheter shaft.

11. The catheter of claim 10, wherein the work element is an inflatable balloon.

12. The balloon catheter of claim 10, wherein the guidewire includes a flexible terminal section distal to the protruding section, the terminal section having an outer diameter substantially equal to an outer diameter of the section of the guidewire proximal to the protruding section.

13. The balloon catheter of claim 12, wherein the terminal section has a length that is sufficient to cross common intravascular occlusions.

14. The balloon catheter of claim 10, wherein the protruding section has a generally teardrop shape, a tapered portion thereof pointing in the distal direction.

15. The balloon catheter of claim 10, wherein the protruding section has a generally right circular conical shape, with atraumatic rounded edges.

16. The balloon catheter of claim 10, wherein at least one of the catheter shaft and the center shaft includes one of a wire, a spirally wound coil and a wire braid embedded therein or wound thereabout, to enhance torqueability of the catheter in tortuous and tight vessels.

17. The balloon catheter of claim 10, wherein the terminal section of the guidewire includes a coil wound about an outer diameter thereof.

18. The balloon catheter of claim 12, wherein a distal most portion of the terminal section is shaped to facilitate navigation through tortuous vessels.

19. A method for crossing an intravascular occlusion using a catheter and a guidewire including a distal tapered protruding section and a flexible terminal section distal to 15 the protruding section, comprising the steps of:

advancing the guidewire through a patient's vasculature until the occlusion is reached;

further advancing the guidewire until the terminal section crosses the occlusion and the tapered protruding section reaches the occlusion;

sliding the catheter over the guidewire by pushing a proximal end thereof until a distal end of the catheter abuts a proximal surface of the tapered protruding section; and

while applying a biasing force to the guidewire in a proximal direction, pushing the proximal end of the catheter to advance both the tapered protruding section of the guidewire and the catheter distal end until the occlusion is crossed;

whereby, the tapered protruding section and the distal end of the catheter together present a substantially smoothly tapered profile to the occlusion.

20. The method of claim 19, wherein the catheter has a torqueable shaft, and wherein the sliding and pushing steps also includes applying torque to the proximal end of the catheter, the torque being transmitted via the torqueable shaft to the distal end thereof

21. A percutaneous transluminal coronary angioplasty (PTCA) balloon catheter, comprising:

a center shaft, the center shaft including an axial guidewire lumen;

a catheter shaft, the catheter shaft including an axial lumen therethrough in which the center shaft is disposed, at least one of the catheter shaft and the center shaft including one of a wire, a coil and a wire braid embedded therein or wound about an outer diameter thereof, and

an inflatable balloon disposed near a distal end of the catheter shaft,

whereby, the wire, coil or wire braid enhances a torque transmission ability of the PTCA catheter.

22. The PTCA catheter of claim 21, wherein the coil is one of single and multifilar.

23. The PTCA catheter of claim 21, wherein at least one of the catheter and center shafts comprises at least one material selected from the group consisting of PEBAX, polyurethane, nylon and polyimide.

24. The PTCA catheter of claim 2 1, further comprising a guidewire slidably disposed within the guidewire lumen, the guidewire including an integral and tapered protruding section near a distal tip thereof.

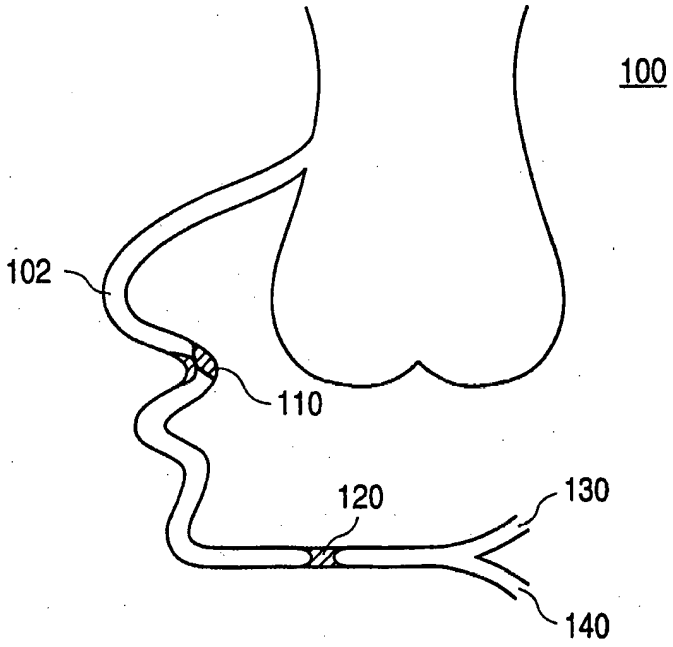


FIG. 1

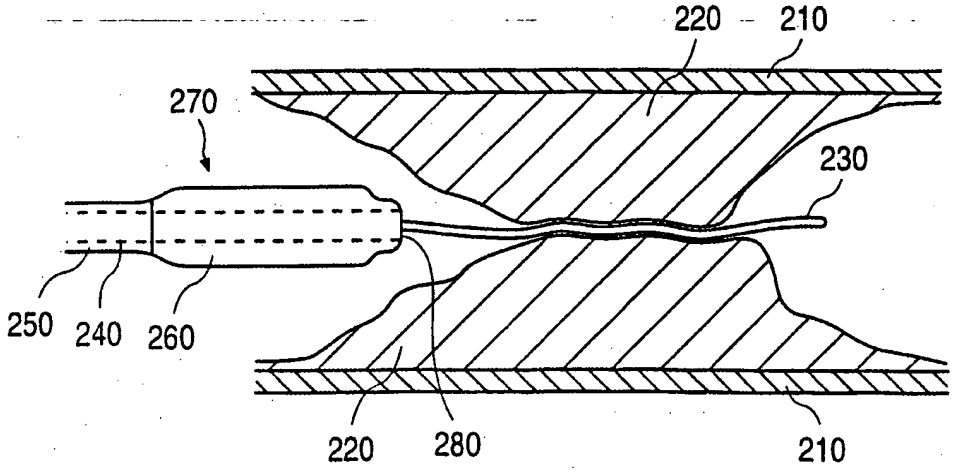


FIG. 2

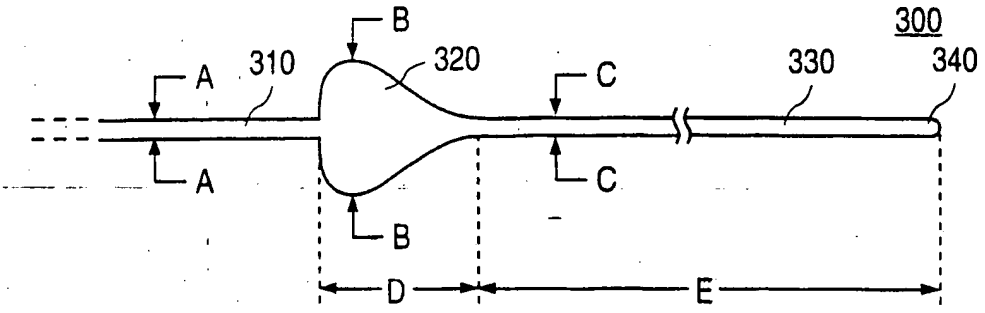
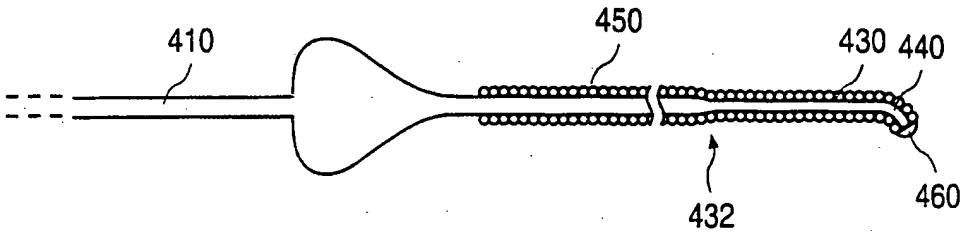


FIG. 3



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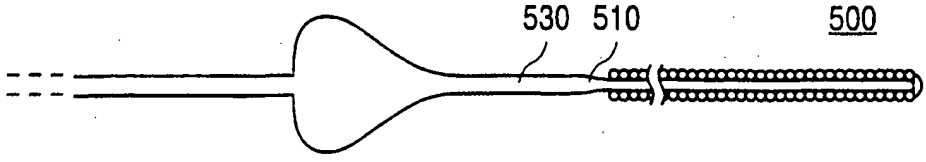

FIG. 5

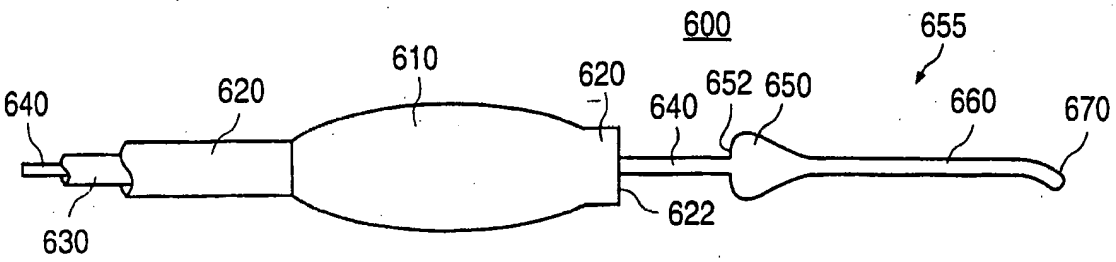
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FIG. 6A

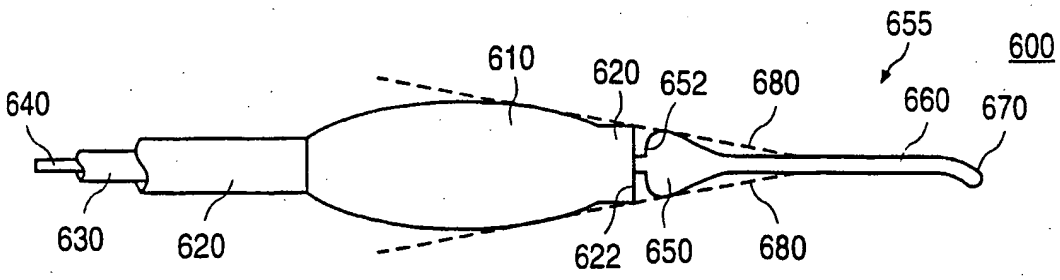
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FIG. 6B

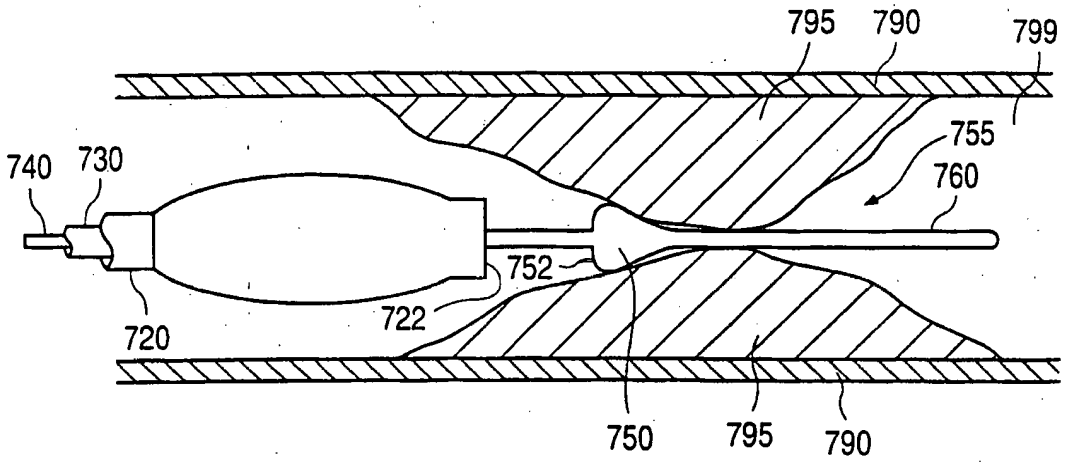
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FIG. 7A

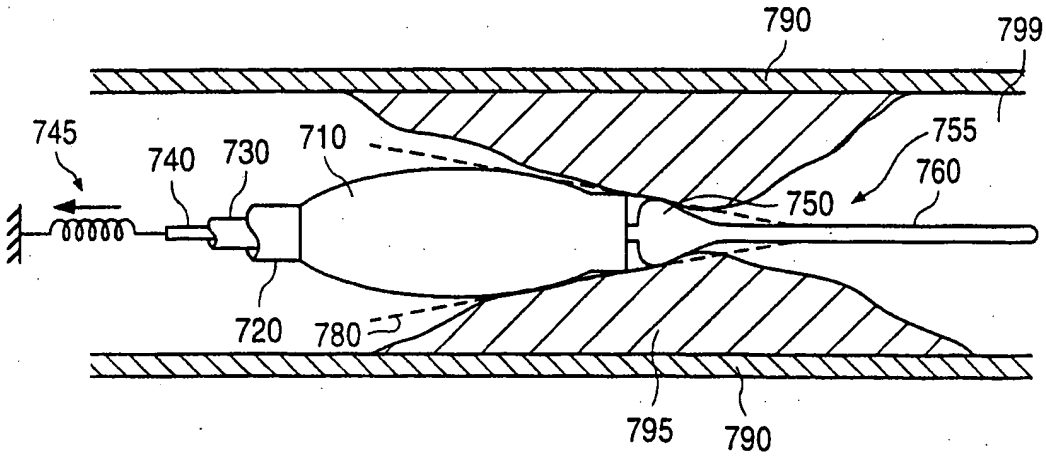
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FIG. 7B

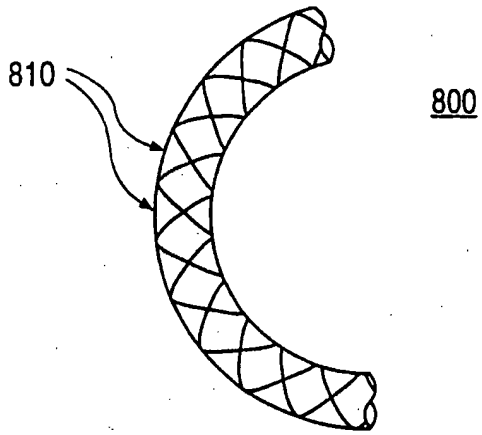

FIG. 8

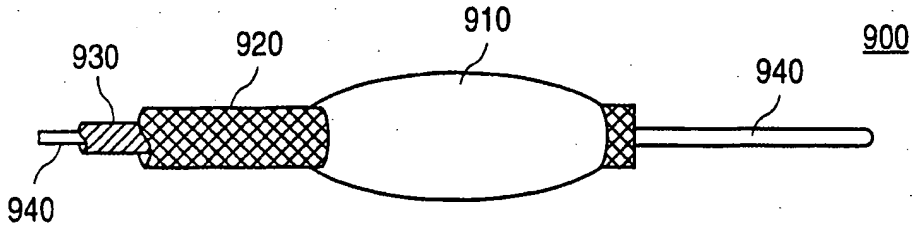

FIG. 9

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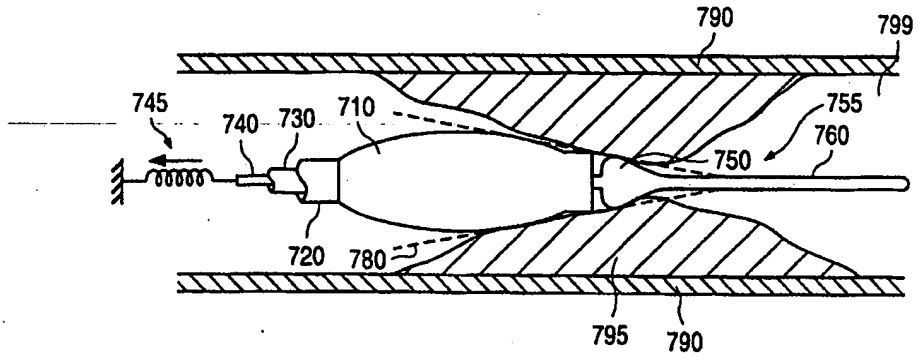
(54) Title: IMPROVED GUIDEWIRE, CATHETER AND METHOD OF CROSSING TIGHT INTRAVASCULAR OCCLUSIONS USING SAME



(57) Abstract

A guidewire includes a proximal section; a distal section; and a protruding section, the protruding section being integral with the guidewire and disposed between the proximal and distal sections. The protruding section tapers in the distal direction to smoothly join with the distal section. According to another aspect of the invention, an intravascular catheter includes a catheter shaft having a work element attached to a distal section thereof; a center shaft disposed axially within the catheter shaft, the center shaft having a guidewire lumen therethrough, and a guidewire slidably disposed within the guidewire lumen, the guidewire including an integral and tapered protruding section near the distal tip thereof. When the guidewire is fully proximally retracted, the proximal surface of the protruding section faces and abuts against a corresponding distal–most surface of the catheter shaft to present a gradual transition from the guidewire to the distal section of the catheter shaft. According to another aspect, the present invention provides a percutaneous transluminal coronary angioplasty balloon catheter including a catheter and center shaft, both of which include an axial lumen therethrough. An inflatable balloon is disposed near the distal end of the catheter shaft. The center shaft is disposed within the axial lumen of the catheter shaft. One or both of the catheter and center shafts include either a wire, a coil or a wire braid embedded therein or wound about an outer diameter thereof to enhance torqueability of the balloon catheter.

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INTERNATIONAL SEARCH REPORT

In: itional Application No
PCT/US 99/06498

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M25/01

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 454 788 A (GHAERZADEH KAMBIZ ET AL) 3 October 1995 (1995-10-03) the whole document	1-9
X	US 5 385 152 A (MCLAUGHLIN PAUL D ET AL) 31 January 1995 (1995-01-31) the whole document	1-5,9-15
X	EP 0 396 074 A (STERIMED GMBH) 7 November 1990 (1990-11-07) the whole document	1-18
X	US 5 465 733 A (HINOHARA TOMOAKI ET AL) 14 November 1995 (1995-11-14) the whole document	1-18
A	reinforced section 104	21-24

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
5 October 1999	12. 10. 1999

Name and mailing address of the ISA	Authorized officer
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INTERNATIONAL SEARCH REPORT

In ational Application No
PCT/US 99/06498

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 364 357 A (AASE BRENDA L) 15 November 1994 (1994-11-15) the whole document	21-23
X	US 5 176 661 A (EVARD PHILIP C ET AL) 5 January 1993 (1993-01-05) the whole document	21-23

3

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 99/06498

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 19 20
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [X] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[X] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-18

   A guidewire including a tapered protruding section

2. Claims: 21-24

   A balloon catheter having a catheter shaft and a centre shaft, one of which includes reinforcing means to enhance torqueability.